

CLAIMS

1. Process for preparing modafinil having a defined granulometry which comprises the steps of:

- 5 a) preparing a solution of DMSAM in a solvent ;
 b) contacting the solution obtained with NH_3 at a predetermined temperature and under a predetermined stirring; and
 c) isolating the modafinil formed,

10 wherein said temperature and said stirring are predetermined in order to obtain said defined granulometry.

2. Process according to claim 1, wherein the solvent is a protic polar solvent.

15 3. Process according to claim 2, wherein the solvent is an alcohol.

4. Process according to claim 3, wherein the solvent is methanol.

20 5. Process according to claim 4, wherein the solution of DMSAM has a concentration of DMSAM of between 1 and 1.25 mol L^{-1} .

6. Process according to any one of the preceding claims, wherein the temperature in step b) is held between 15 and 65°C .

25 7. Process according to any one of the preceding claims, wherein the predetermined stirring speed in step b) is chosen such that the modafinil isolated in step c) has a granulometric median of between 2 and $60 \mu\text{m}$, preferably between 15 and $45 \mu\text{m}$.

30 8. Process according to any of the preceding claims, wherein in step b), the solution of DMSAM is contacted with 3 to 6 molar equivalent of NH_3 .

9. Process according to claim 8, wherein, in step b), the solution of DMSAM is contacted with 3.2 and 5 molar equivalent of NH_3 .

5 10. Process according to any of the preceding claims, wherein, in step b), the NH_3 is introduced into the solution over a sufficient time to obtain a complete dissolution of NH_3 .

10 11. Process according to claim 10, wherein, in step b), the NH_3 is introduced into the solution over a time of between 2 h and 6 h.

12. Process according to Claim 11, wherein, in step b), the NH_3 is introduced into the solution over a time of between 3 h and 4.5 h.

15 13. Process according to any of the preceding claims, wherein, in step b), the solution is contacted after the introduction of the NH_3 for a contact time sufficient to allow the polymorphic transformation of form III to form I.

20 14. Process according to claim 13, wherein the contact time is between 8 and 12 h.

25 15. Process according to any of the preceding claims, wherein the solution obtained after step b) is further maintained at a temperature lower than the predetermined temperature of step b) for a time sufficient to obtain complete crystallization of modafinil.

16. Process according to claim 15, wherein the solution is further maintained at a temperature lower than the temperature of step b) for a time of from 1 h to 4 h.

17. Process according to claims 15 and 16, wherein the temperature is between -20°C and 0°C.

18. Process according to any of the preceding claims, wherein the
5 modafinil is isolated in step c) by filtration.

19. Process according to any of the preceding claims, wherein the solvent in step a) comprises water.

10 20. Process according to claim 19, wherein the solvent contains from 5% to 20% by volume of water.

21. Process according to any of claims 19 or 20, wherein the NH₃ is introduced into the solution in step b) over a time of between 4 h and 5 h.

15 22. Process according to any of claims 19 to 21, wherein, in step b), the solution of DMSAM is contacted with 5 to 5.5 molar equivalent of NH₃.

23. Process according to any of the preceding claims, which does not include a recrystallization step after step c).

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24. Process according to any of the preceding claims, which does not include a grinding step after step c).

25 25. Process according to any of the preceding claims, wherein the predetermined temperature and stirring speed are chosen such that particles of modafinil form I of which at least:

- 50% have a diameter of less than 45 µm, and
- 80% have a diameter of less than 110 µm, and
- 95% have a diameter of less than 220 µm,

30 are isolated in step c).

26. Process according to any of claims 1 to 12 and 15 to 24, wherein the modafinil isolated in step c) is modafinil form III.

5 27. Process according to any of claims 1 to 24, wherein the modafinil isolated in step c) is modafinil form I.

28. Process according to any of claims 1 to 24, wherein modafinil with a granulometric median of between 1 μm and 1 mm is isolated in step c).
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29. Process according to claim 1, wherein the levorotary enantiomer of DMSAM is employed in step a).

30. Process according to claim 1, wherein the dextrorotary enantiomer of DMSAM is employed in step a).
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31. A modafinil obtainable by the process according to any of the preceding claims.